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To: Medical Cannabis Policy Advisory Board

From: Trevor Eckhoff, policy analyst, Center for Medical Cannabis

Released: July 12, 2023

Subject: Servings and milligram-per serving labeling for orally

administered medical cannabis products

Introduction

In regards to the subject of this memorandum, the board is asked to answer the following questions:

- 1. Should servings and milligrams of certain cannabinoids per serving be required on orally administered medical cannabis products?
 - a. What cannabinoids should be required?
- 2. Where should this information be required to appear?
 - a) On the container or package?
 - i) on the fact panel; or
 - ii) on the product label?
 - b) On a pharmacy's website?
- 3. For liquid products, should a measuring device be included by the processor?

Once these questions are answered, the board may recommend language to be included as an amendment to Utah Department of Agriculture and Food (UDAF) administrative rules.

Background

Utah law requires that orally administered medical cannabis products (tablets, capsules, gummies, chews, gelatin cubes, lozenges, liquid suspensions, and sublingual preparation products) provide on their fact panels total composite



tetrahydrocannabinol (THC), cannabidiol (CBD), and any known cannabinoid that is greater than 1% of the total cannabinoids present.¹ However, Utah law doesn't require orally administered medical cannabis product labels or fact panels to convey cannabinoid milligram content per individual piece or milliliter, nor a standard serving size. Some Utah processors independently share milligrams per serving for their orally administered products, typically found on the package label or on the fact panel, adjacent to total milligram content. For infused edibles such as tablets, capsules, or gummies, this may read as "X mg per piece." For liquid suspension products like tinctures, a measuring cup or dropper with milliliter hash marks accompanies milligrams per milliliter information on the bottle, such as "X mg per 1 ml."

For example, a package containing 10 capsules totaling 100 mg of THC must be labeled as such, but the label is not required to expressly state each capsule contains approximately 10 mg of THC. Additionally, processors are not required to define 1 (one) 10 mg capsule as a standard serving. Processors that include cannabinoid milligrams per serving vary in which cannabinoids they choose to disclose. The primary advertised cannabinoid(s), most often THC and CBD, are common choices. Others may include various cannabinoids relevant to the products' intended effect.

Analysis

Currently, only some medical cannabis pharmacies carry orally administered medical cannabis products labeled with milligrams per serving. For pharmacies that don't carry infused edible products with this information, pharmacy medical providers (PMPs) and patients can determine milligram content per serving by dividing total milligram content from the total servings per package. However, a product with more than one advertised cannabinoid, such as a 2:1 CBD/THC ratio, is more difficult to calculate. Liquid suspension products can cause more difficulty

¹ UCA 4-41a-602 (1)(a)(ii)



for a patient, as attempting to measure cannabinoid content without a measurement tool and a manufacturer-specified serving provides no definitive answer.

Dosing considerations

The inclusion of milligrams per serving on an orally administered product is not necessarily a dosing instruction from the processor. Determination of a proper dose amount is the responsibility of a recommending medical provider (RMP) or PMP. However, this does not preclude a processor from developing a standard serving for their product. The standards developing organization *ASTM International* recommends that orally administered cannabis products state total milligrams of THC, CBD, and other relevant or legally required cannabinoids, "expressed in milligrams per manufacturer specified serving/servings per container."²

Other states' dosing laws

- At least 16 states set their THC limit for orally administered cannabis products to 10 mg "per serving" or "in a single serving," meaning one piece or per a measurement in milliliters.
 - Note: these states do not prohibit consumption beyond the "serving."
 The language is intended to partition the product's contents into easily discernible, measurable units.
- At least 12 states with a medical cannabis program require serving information directly on orally administered cannabis products' labels.
 - 5 states and 1 territory require THC and CBD listed per serving.
 - 2 states require per serving information for "any other marketed cannabinoid" or "any other cannabinoid listed or described in the label or packaging."

² "Standard Guide for Packaging and Labeling of Consumer Resin Cannabis Products for Sale to Adult Consumers, Legally Authorized Medical Users, and Caregivers in a Business-to-Consumer Retail Environment (Retailers)." ASTM, ASTM International, March 11, 2019, 5. https://www.astm.org/d8233-19.html



- At least 7 states require physical demarcation, separation, or individual wrapping of edibles per serving.
- 5 states require the product to include a measuring device, if applicable.

Basis for including servings on product labels

A basis for requiring serving information on product labels is to address the potential for overconsumption and patient confusion. According to the Utah Poison Control Center, reported cannabis exposures have more than doubled since 2017. Due to increased access to legal and illegal cannabis products, accidental consumption and overconsumption continue to be a legitimate concern. The Centers for Disease Control and Prevention cautions users of orally administered cannabis products to be aware of greater risk of poisoning due to its delayed effects, longer period of intoxicating effects, and unpredictability. Providing a serving may alleviate some cases of patient confusion regarding dosing and prevent cases of overconsumption. In addition, should a user consume orally administered cannabis and require medical attention, serving information may assist in the reporting of the ingested amount to medical personnel.

Industry impact

New requirements for servings and milligram-per serving information would require processors to alter current packaging processes, including redesigning labels and potentially having to switch to new packaging. Additionally, what cannabinoids should be included per serving must be considered. Generally, states with existing regulations only require THC per serving to be listed due to its psychoactive properties, although some additionally require CBD or other advertised cannabinoids. Some Utah processors list other cannabinoids on their product labels, particularly if they are advertised as multi-cannabinoid products. Examples include:

- a) Solely THC;
- b) THC and CBD; or
- c) THC, CBD, and additional advertised cannabinoids.



It is important to note that any requirement would continue to allow processors to label cannabinoid contents with a 10% or lower variance from verified content amounts found in lab testing.

UDAF allows two options for providing information with medical cannabis products; either on the fact panel directly affixed to the immediate container, on the product's container or directly attached to the product. Allowing inclusion of servings and milligrams per serving on either the fact panel or label would provide processors greater flexibility to choose which option works best for their packaging, but there would be added cost for attaching labeling tags to packages. **Attachment A** contains examples of Utah processors including servings and milligram content per serving in various ways.

Online ordering is an additional consideration. According to sales data, nearly one-third of all medical cannabis orders occur online. For products that do not have available pictures or cannot be magnified, serving information would need to be included in the product description.

Options

Board action on this item could include requesting UDAF to draft rule changes for presentation at the board's next meeting, which could be approved for recommendation. Alternatively, the board may vote to table this item or not take action at this time.

- 1. Should servings and milligrams of certain cannabinoids per serving be required on orally administered medical cannabis products?
 - a. What cannabinoids should be required?

A draft rule would amend Utah Administrative Code R68-28, Cannabis Processing, to add a requirement that for products intended to be ingested, the amount of total



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THC and any advertised cannabinoid in milligrams per serving must be listed on the fact panel or product label.

2. Where should this information be required to appear?

- a. On the container or package?
 - i. On the fact panel; or
 - ii. On the product label?
- b. On a pharmacy's website?

Requiring this information on a pharmacy's website would entail a separate rule change from R-68-28, which would additionally be presented to the board.

3. For liquid products, should a measuring device be included from the processor?

This potential requirement would also fall under a separate rule. Common measuring devices include droppers with milliliter hash marks, cups with similar hash marks, and disposable tea or tablespoons.

Conclusion

Board members may contact Trevor Eckhoff at the DHHS Center for Medical Cannabis (teckhoff@utah.gov) if they have any questions prior to the board meeting. In addition, board members are encouraged to solicit feedback from the respective stakeholders they represent.